

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30437 A1

- (51) International Patent Classification⁷: A61N 1/00
- (21) International Application Number: PCT/US00/29730
- (22) International Filing Date: 27 October 2000 (27.10.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/161,989 28 October 1999 (28.10.1999) US
- (71) Applicants (*for all designated States except US*): WINCHESTER DEVELOPMENT ASSOCIATES [US/US]; 58 Wedgemere Avenue, Winchester, MA 01890 (US). ENTERPRISE MEDICAL TECHNOLOGY, INC. [US/US]; 20 Acorn Park, Cambridge, MA 02140-2390 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (*for US only*): MARTINELLI, Michael, A. [—/US]; 58 Wedgemere Avenue, Winchester, MA 01890 (US).
- (74) Agents: LAPPIN, Mark, G. et al.; McDermott, Will & Emery, 28 State Street, Boston, MA 02109 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.
— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 01/30437 A1

(54) Title: PATIENT-SHIELDING AND COIL SYSTEM

(57) Abstract: A patient-shielding and coil system, including a coil wire (12, 14) electrically coupled to a source of electrical current, an electrically conductive surface (76), insulation material (74) between the coil wire (12, 14) and the conductive surface (76), and a drain wire (42) connected to the conductive surface (76) and forming a capacitive current loop with respect to the source.

WO 01/30437

PCT/US00/29730

PATIENT-SHIELDING AND COIL SYSTEM

5 BACKGROUND OF THE INVENTION

The present invention relates to, a patient-shielding system for use when a patient is exposed to capacitive currents as a result of immersion into a time-varying magnetic field. More particularly, this invention relates to a system for redirecting potentially harmful currents away from organs such as the heart when a medical procedure includes
10 exposing that organ to a time-varying magnetic field.

Systems and methods for determining the position and orientation of surgical probes based on the use of magnetic fields are known. See, for example, U.S. Patent 5,592,939. Such systems and methods generally rely on the presence of a time varying magnetic field in the surgical region of interest. An exemplary navigation system is
15 shown in FIG. 1. The exemplary system of FIG. 1 contains platform 10 in which is embedded coils for generating a time-varying magnetic field. Two such coils are depicted as first coil set 12 and second coil set 14. Field line 22 depicts the orientation of a magnetic field amplitude at an instant of time. See also U.S. Patent 5,592,939.

Present techniques for projecting a time varying magnetic field into a surgical
20 region of interest preferably position the patient proximal to the coils that are generating the necessary fields. This is depicted in FIG. 2. Patient 24 is generally kept from direct contact with coil sets 12 and 14 by non-conducting layer 20. As a result of this relationship, there are times when coil sets 12 and 14, located proximally to the surgical region of interest, may have differing voltage potentials. By way of example only, in
25 FIG. 2, coil set 12 is at positive potential 16, and coil set 14 is at negative potential 18. A uniform amplitude field that has its major component lateral to a plane determined by an operating room table is thus generated by two coils at different voltage potentials separated along that lateral dimension. Field line 22 in FIG.2 indicates the direction of such an amplitude. In the relationship indicated in FIG. 2, the surgical region of interest
30 has loop characteristics of what is known as a capacitive current. A schematic of such a current is depicted in FIG. 3. For a time-varying magnetic field where the frequency is of the order of $f = 20$ kilohertz and the difference between positive potential 16 and

WO 01/30437

PCT/US00/29730

negative potential 18 is $V = 25$ volts, capacitive current 34, denoted by I , can exceed what is considered desirable. For example, typical safety standards, such as those of Underwriter Laboratories, require that the current through a patient be less than $I = 10$ microamps. For insulating layer 20 with capacitance 30 of the order of $C = 10^{-10}$ farads, and where patient 24 has a resistance 32 of approximately 100 ohms, capacitive current 34 is of the order

$$I = V (2 \pi f C) = 345 \text{ microamps}$$

This is well in excess of a 10 microamp current.

In light of the foregoing, it is desirable to reduce the magnitude of the capacitive current introduced by a magnetic field coil within a surgical region. It is an object of the present invention to substantially overcome the above-identified disadvantages and drawbacks of the prior art.

SUMMARY OF THE INVENTION

The foregoing and other objects are achieved by the invention which in one aspect comprises a patient-shielding and coil system, including a coil wire electrically coupled to a source of electrical current, an electrically conductive surface, insulation material situated between the coil wire and the conductive surface, and a drain wire connected to the conductive surface and forming a capacitive current loop with respect to the source.

In another embodiment of the invention, the conductive surface has a resistance of substantially 1 ohm per square.

In another embodiment of the invention, the electrically conductive surface forms an incomplete enclosure of the coil wire, so as to create an incomplete electrical circuit.

In another embodiment of the invention, the conductive surface includes an upper portion and a lower portion.

In another embodiment of the invention, the conductive surface includes a polyester foil, vapor deposited with aluminum.

WO 01/30437

PCT/US00/29730

BRIEF DESCRIPTION OF DRAWINGS

The foregoing and other objects of this invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings in which:

5 FIG. 1 depicts an exemplary coil system for generating a uniform amplitude magnetic field for a navigational system.

FIG. 2 depicts an effect the exemplary system of FIG. 1 can have on a patient.

FIG. 3 is a circuit diagram of a capacitive current loop formed by the configuration of FIG. 2.

10 FIG. 4 depicts an exemplary patient-shielding and coil system consistent with the present invention.

FIG. 5 depicts a cross section of a portion of the exemplary system of FIG. 4.

FIG. 6 depicts an example of how current flows across a cross section of the exemplary system of FIG. 4.

15 FIG. 7 depicts an alternative exemplary patient-shielding and coil system consistent with the present invention.

FIG. 8 depicts a side view of the exemplary patient-shielding and coil system of FIG. 7.

20 DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a system for redirecting potentially harmful currents away from organs such as the heart when a medical procedure includes exposing that organ to a time-varying magnetic field.

25 FIG. 4 depicts a patient-shielding and coil system in accordance with a preferred embodiment of the present invention. The ends of coil wire 44 are attached to a driving voltage source (not shown). Between the ends of coil wire 44 and the coil assembly 40, coil wire 44 is wrapped about itself as twisted pair 47. Within coil assembly 40, coil wire 44 is looped N times. The current along coil wire 40 is denoted I_M . Thus, in the absence of any other effects, the net current around coil assembly 40 is NI_M .

30 Also depicted in FIG. 4 is coil form 54. Coil form 54 surrounds that portion of coil wire 44 where coil wire 44 is looped N times. Coil form 54 is depicted in FIG. 4 as

WO 01/30437

PCT/US00/29730

rectangular in shape, but other shapes such can be used as well, and are consistent with the present invention. Other embodiments of the invention may include a coil wire 44 without a coil form, such that the coil wire is looped without the benefit of any coil form.

Also depicted in FIG. 4 is drain wire 42 and shield 52, depicted as the dashed
5 line. The shield 52 is preferably electrically conductive, so as to support an electrical current in the presence of a voltage potential. In some embodiments, the shield 52 may include a non-conductive foundation bonded, or otherwise attached, to a conductive surface. Drain wire 42 is attached, or otherwise mounted, to shield 52. Shield 52 extends along twisted pair 47 and envelops most of coil form 54, and thus envelops
10 most of coil wire 44. However, shield 52 does not form a complete enclosure around coil axis 45, so as to prevent a compensating current from forming along the surface of shield 52 that would serve to decrease the magnitude of the magnetic field produced by the coil assembly 40. Thus, shield 52 ends at gap 46.

A more detailed cross section of coil assembly 40 consistent with a preferred
15 embodiment of the present invention is shown in FIG. 5. Shield 52 is exterior of coil form 54. The lower portion of shield 52 is depicted as "U" shaped, and the upper portion of shield 52 is depicted as a cover. The lower and upper portions of shield 52 can preferably be connected by conductive silver ink at location 56, but other techniques of connectivity using any type of conducting material can also be used. Shield 52 can be
20 composed of a polyester foil with aluminum vapor-deposited on its surface, but other compositions with the resistance discussed below can also be used. The resistance of the vapor-deposited aluminum, a thin film, used in one embodiment of the present invention is of the order 1 ohm per square. The unit "ohm per square" is a unit of resistance known in the art appropriate for discussions of thin film material. Drain wire 42 is connected to
25 shield 52 and is connected to ground. Drain wire 42 carries the current I_C along the length of shield 52. At each point along shield 52 the current I_C in drain wire 42 is the total of all current induced between that point and gap 46. Because of the ground connection, these are capacitive currents as discussed above with regard to patient 24. However, here the capacitive current loop is closed with respect to a ground rather than
30 through patient 24. The current I_C , at an instant of time, is associated with positive

WO 01/30437

PCT/US00/29730

potential 16 and the capacitance of coil form 54, where the current loop of interest is completed by shield 52 connected to ground via drain wire 42.

Also depicted in the cross section shown in FIG. 5 are the N cross sections of coil wire 44 contained within coil form 54. Because of the presence of current I_C along drain wire 42, the current in coil wire 44 is altered by an amount of the order $I_C/(2N)$. This is depicted in FIG. 6 where drain wire 42 along shield 52 has a current $-I_C/2$ and coil wire 44 along one loop has an adjusted current $I_M + I_C/(2N)$. The net current including the effect of N loops of coil wire 44 and drain wire 42 along coil assembly 40, however, remains the value as before NI_M . The current along drain wire 42 is cancelled. The net result is that patient 24 is shielded from capacitive current 34 by an amount of the order I_C . Nevertheless, the desired magnetic fields for navigation throughout the surgical region of interest remain the same.

FIGS. 7 and 8 depict a patient-shielding and coil system in accordance with another preferred embodiment of the present invention. In FIGS. 7 and 8, shield system 70 is placed over platform 10 containing coil sets 12 and 14. Shield system 70 is depicted as containing vapor-deposited conductive film 76 on top of non-conductive plastic sheet 74. Conductive film 76 is connected to drain wire 42. Coil sets 12 and 14 are connected in series and are driven through twisted pair 47 to produce the desired magnetic fields. Positive potential 16 and negative potential 18 are shielded from patient 24 by the conductive film 76. Vapor-deposited conductive film 76 has a resistance of the order 1 ohm per square. This resistance is sufficient to produce little effect on the magnetic fields, indicated in FIG. 8 by field lines 48. Nevertheless, this resistance is sufficient to protect patient 24 from capacitive current 34.

Experiments performed to measure the effect on navigation of the currents induced in the shield system 70 indicate that these currents are small and have an effect of less than 0.1% on navigation accuracy. The small residual effect can be eliminated by a calibration of the navigating fields in the presence of shield system 70.

Systems consistent with the present invention shield a patient from capacitive currents that arise as a result of patient immersion into a time-varying magnetic field. The foregoing description of implementations of the invention has been presented for purposes of illustration and description. It is not exhaustive and does not limit the

WO 01/30437

PCT/US00/29730

invention to the precise form disclosed. Modifications and variations are possible in light of the above teachings or may be acquired from practicing the invention.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to
5 be considered in respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of the equivalency of the claims are therefore intended to be embraced therein.

WO 01/30437

PCT/US00/29730

What is claimed is:

- 1 1. A patient-shielding and coil system, comprising:
2 a coil wire electrically coupled to a source of electrical current;
3 an electrically conductive surface;
4 insulation material situated between the coil wire and the conductive surface; and
5 a drain wire connected to the conductive surface and forming a capacitive current loop
6 with respect to the source.
- 1 2. A system according to claim 1, wherein the conductive surface has a resistance of
2 substantially 1 ohm per square.
- 1 3. A system according to claim 1, wherein the electrically conductive surface forms an
2 incomplete enclosure of the coil wire, so as to create an incomplete electrical circuit.
- 1 4. A system according to claim 1, wherein the conductive surface includes an upper
2 portion and a lower portion.
- 1 5. A system according to claim 1, wherein the conductive surface includes a polyester foil,
2 vapor deposited with aluminum.

WO 01/30437

PCT/US00/29730

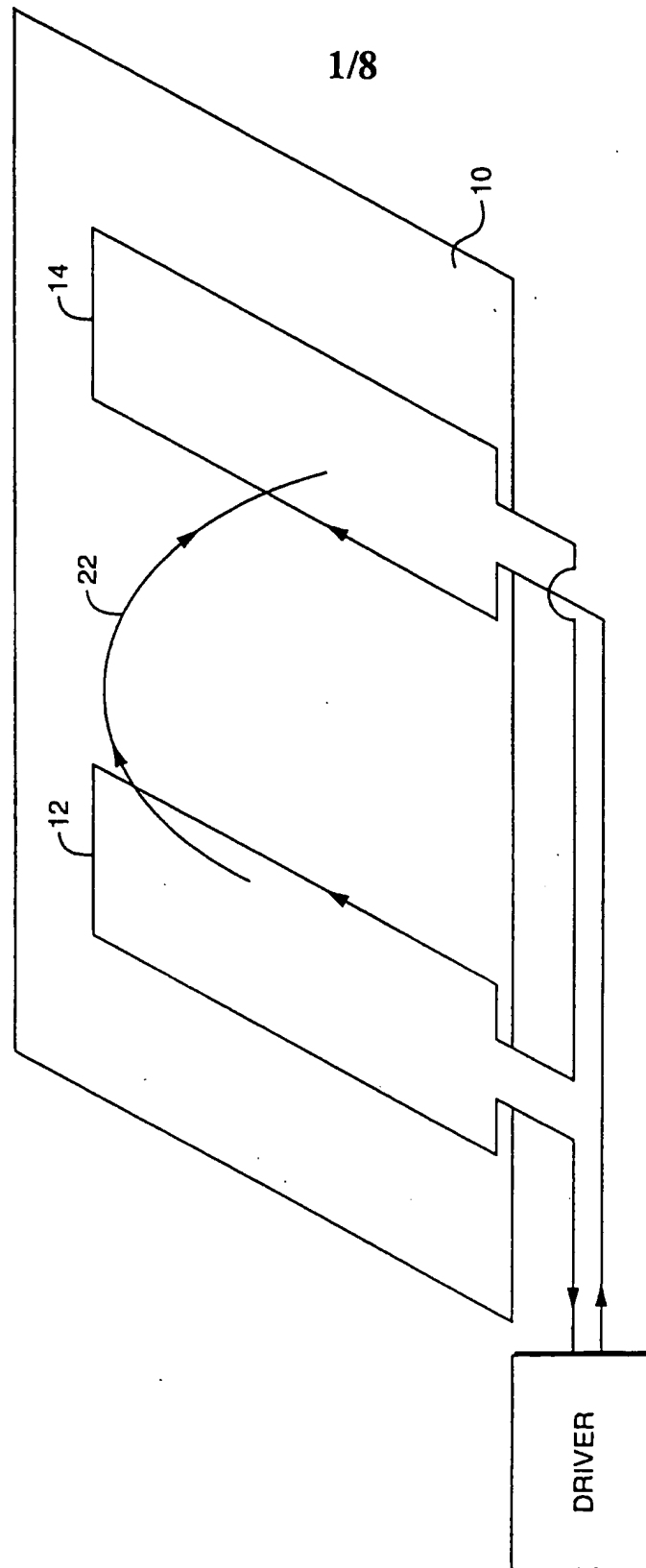


FIG. 1

WO 01/30437

PCT/US00/29730

2/8

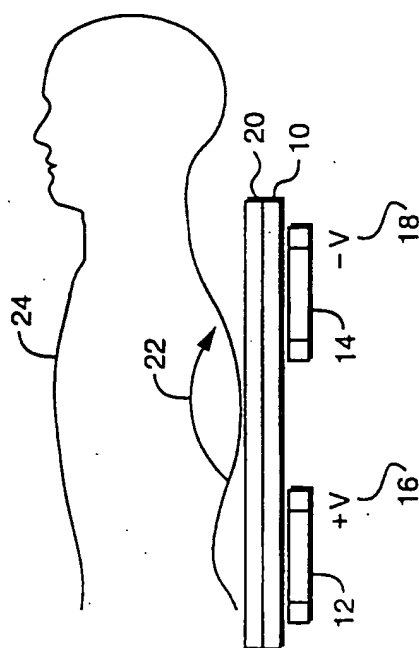


FIG. 2

WO 01/30437

PCT/US00/29730

3/8

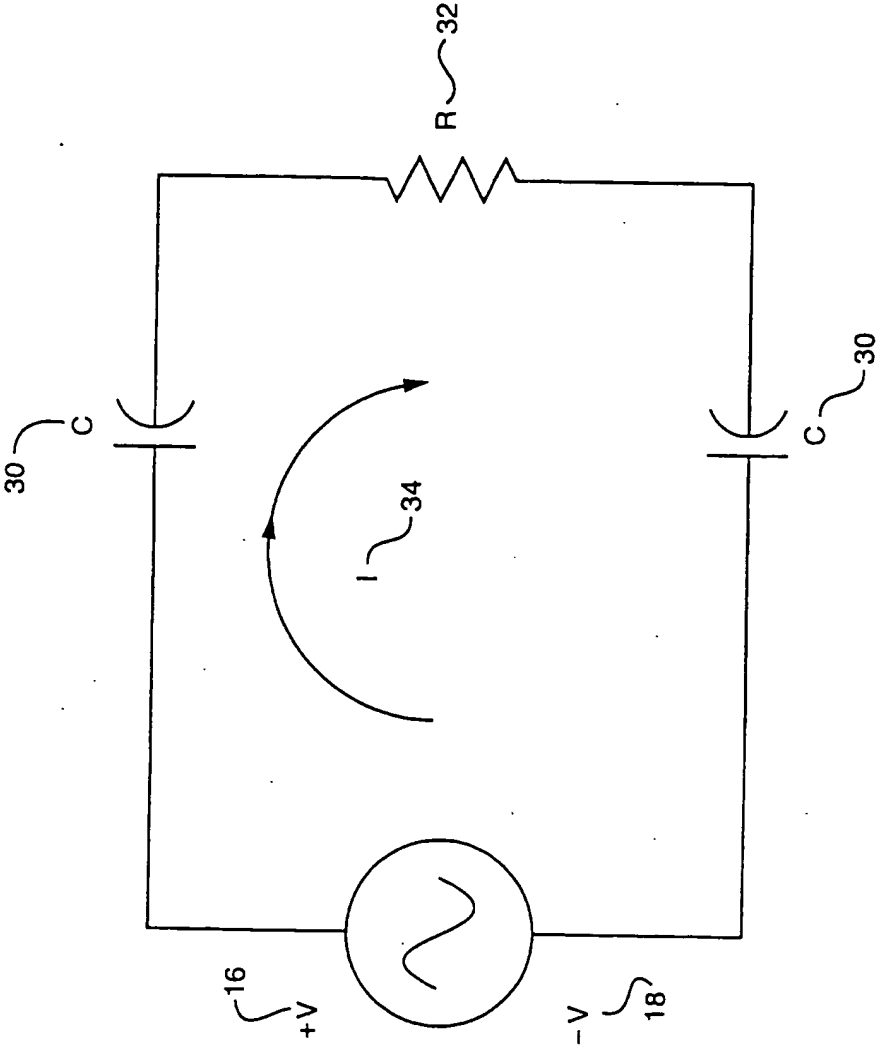
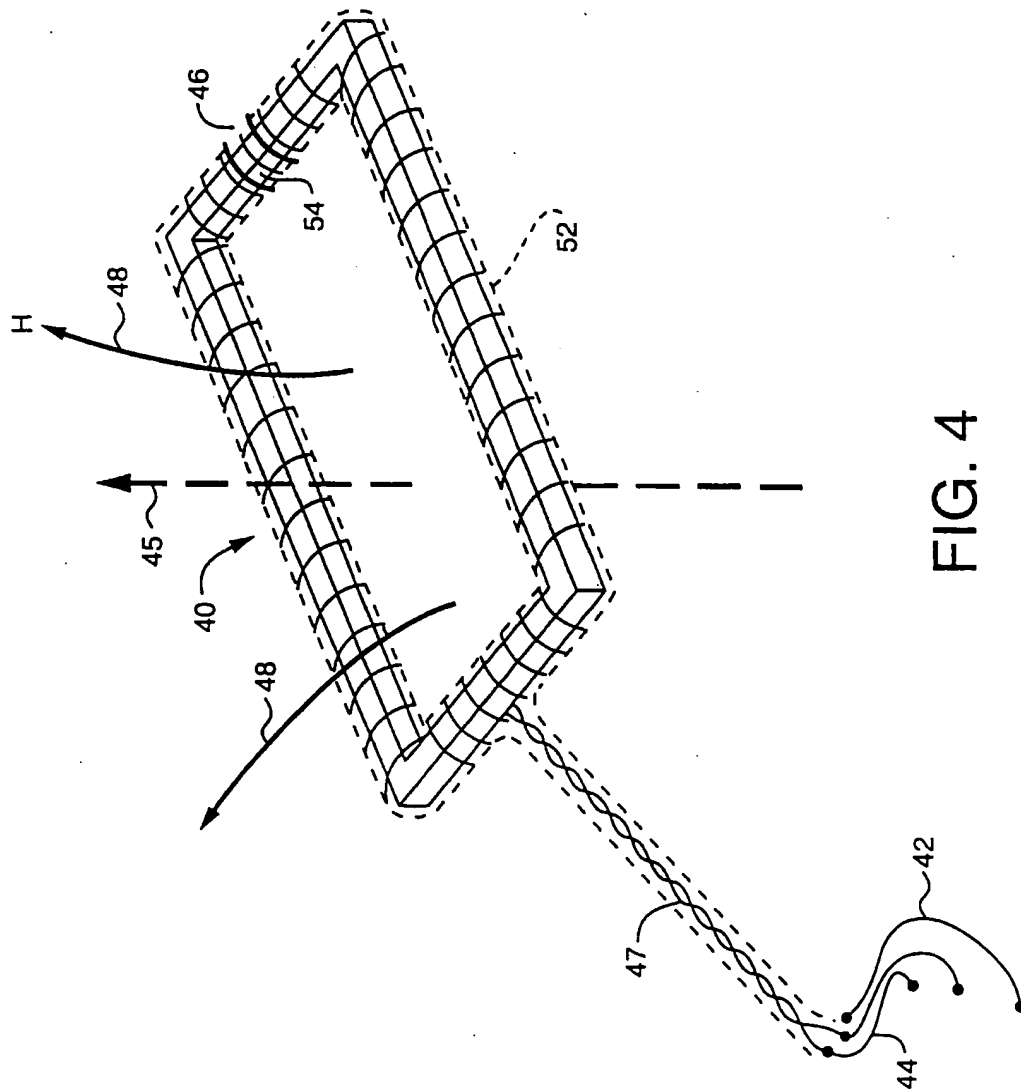


FIG. 3

WO 01/30437

PCT/US00/29730

4/8



WO 01/30437

PCT/US00/29730

5/8

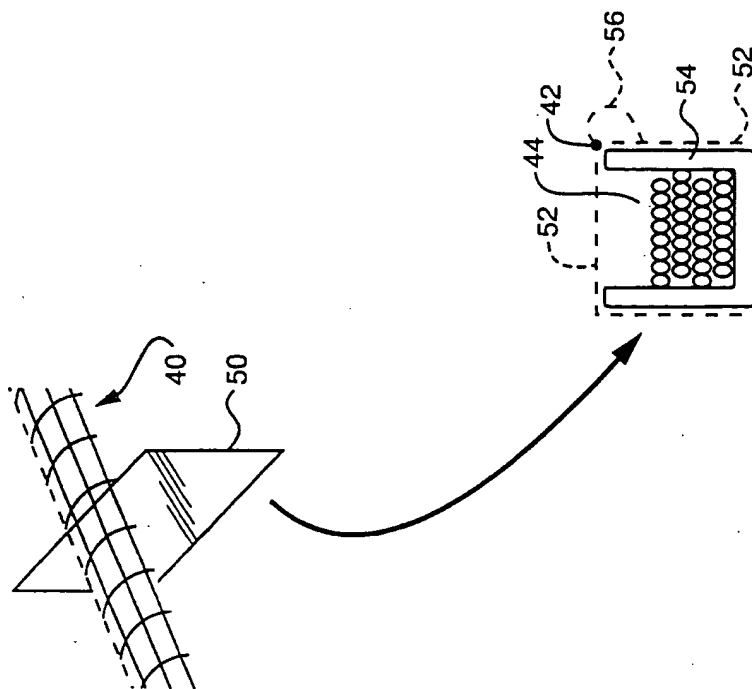


FIG. 5

WO 01/30437

PCT/US00/29730

6/8

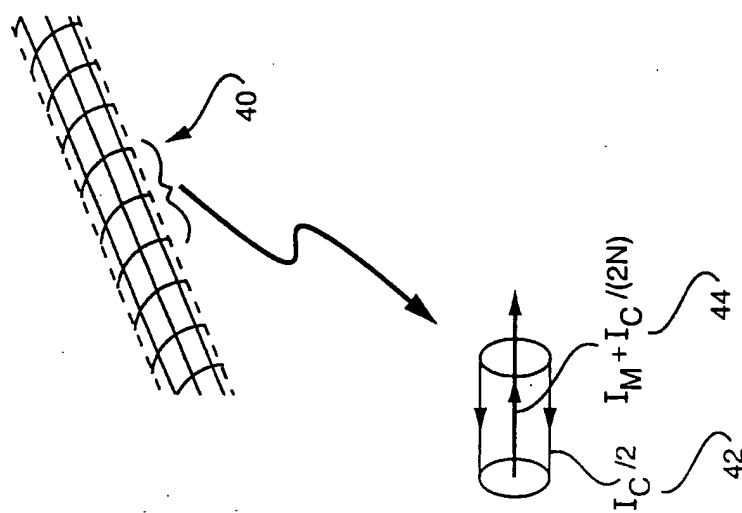


FIG. 6

WO 01/30437

PCT/US00/29730

7/8

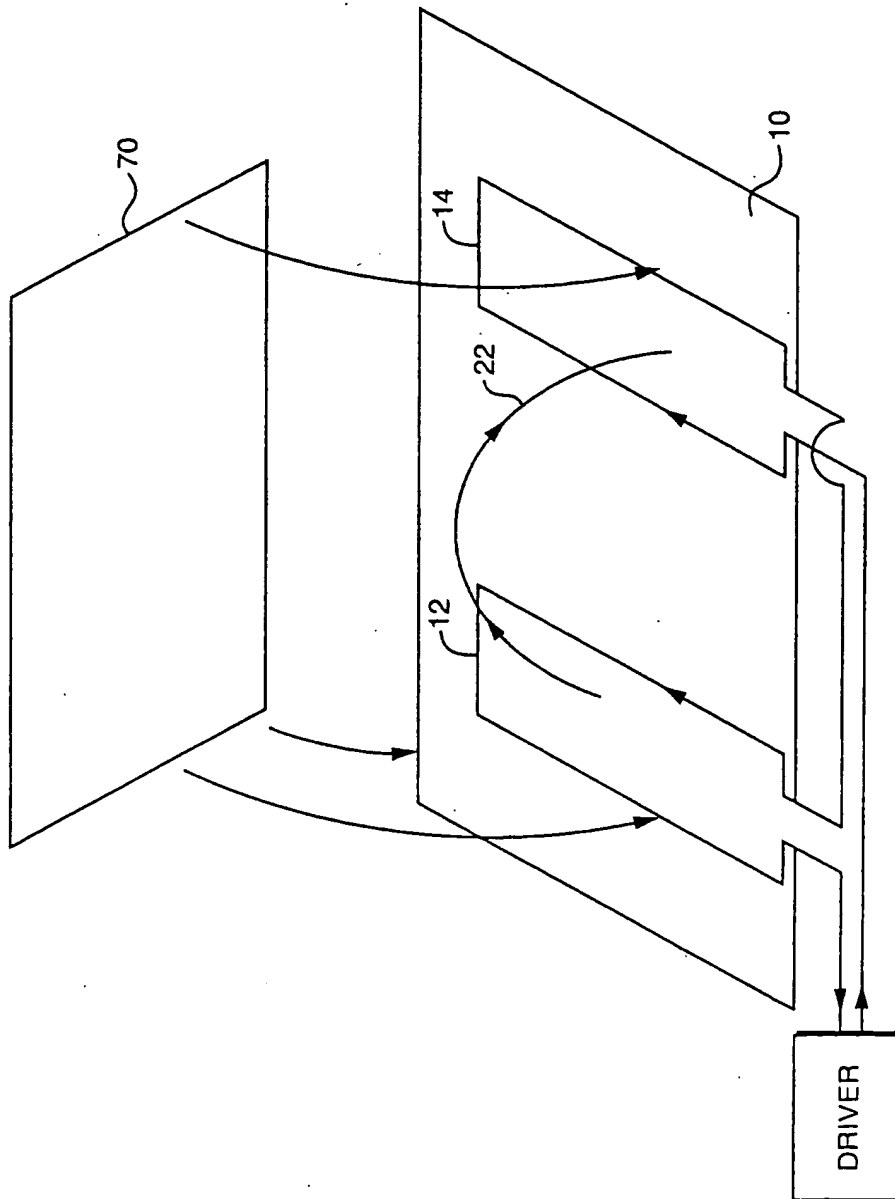


FIG. 7

WO 01/30437

PCT/US00/29730

8/8

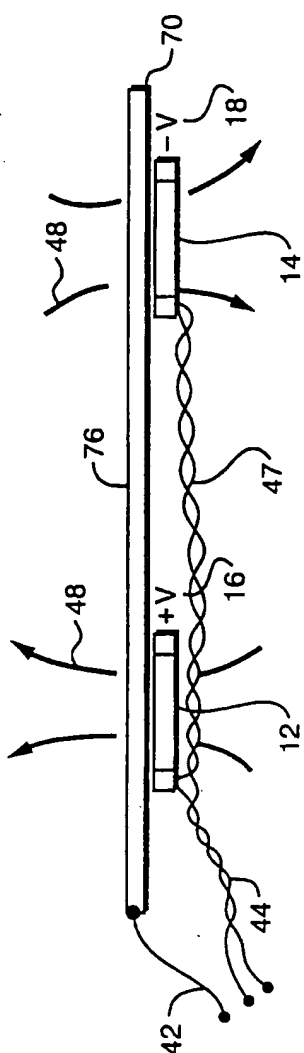


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/29730

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61N 01/00

US CL : 600/013

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/009, 013, 014, 015

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,889,526 A (RAUSCHER et al.) 26 December 1989 (26.12.1989), see entire document.	1-5
A	US 5,030,196 A (INOUE) 9 July 1991 (09.07.1991) see entire document.	1-5
A	US 4,548,208 A (NIEMI) 22 October 1985 (22.10.1985) see entire document.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

26 JANUARY 2001

Date of mailing of the international search report

05 APR 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOSEPH A. CADUGAN

Telephone No. (703) 308-1148